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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,753	11/01/2000	Robert E. Dudley	9774100-0024	2099

7590 01/15/2003  
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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/703,753

Applicant(s)

DUDLEY, ROBERT E

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33,35,36,41,42,45,48,49,57-59,62,64,75-83,88-93,97-99 and 101-210 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims pending in the application are 33,35,36,41,42,45,48,49,57-59,62,64,75-83,88-93,97-99 and 101-210.

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on October 21, 2002 in Paper No. 20 wherein claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 have been amended. Currently, claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are pending in this application.

Applicant's amendment changing the limitations of the base claims to employ the instant composition consisting essentially of the specific ingredients herein in the particular amounts in the claimed methods herein, filed on October 21, 2002 in Paper No. 20 with respect to the rejection of claim 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 made under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (WO 99/24041, of record in the Office Actions November 23, 2001 and April 24, 2001) and Heiber et al. (WO 93/25168, PTO-1449 submitted March 28, 2002 and April 11, 2002), and Omar (5,730,987, of record in the Office Actions November 23, 2001 and April 24, 2001) and Moreland et al. (of record in the Office Actions November 23, 2001 and April 24, 2001) in view of Allen (WO 96/227372, of record in the Office Actions November 23, 2001 and April 24, 2001) for reasons of record stated in the Office Action dated June 5, 2002 have been considered and are found persuasive to remove this particular rejection since the claimed methods herein employing the instant composition consisting essentially of the specific ingredients herein in the particular amounts is not seen to be obvious over the prior art.

Therefore, the said rejection is withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for testosterone disclosed in the specification (see Examples at page 15-29 of the specification herein) in methods herein, does not reasonably provide enablement for improving the efficacy of any pharmaceuticals useful for treating erectile dysfunction in a male subject.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,

- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

In the instant case, "a pharmaceutical" may encompass any pharmaceuticals. However, Applicant's specification provides the experimental results showing that only testosterone was improved the efficacy by employing the instant composition for treating erectile dysfunction in a male subject. Thus, these examples fail to provide sufficient working examples to support the broad use of any "pharmaceutical" in the claimed method for improving the efficacy. Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, the instant claims read on the employment of any "pharmaceutical" in pharmaceutical methods useful in male subject treatments, necessitating one of skill to perform an exhaustive search for the embodiments of "pharmaceutical" suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention absent undue experimentation.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-42 of U.S. Patent No. 6,503,894.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent are drawn to a method for administering a composition to skin of a human subject in need of thereof. The claim of the instant application is drawn to methods for improving the efficacy of a pharmaceutical comprising percutaneously administering the same composition to a male subject. One having ordinary skill in the art at the time the invention was made would have been motivated to administer the same composition herein a method for administering a composition to skin of a human subject in need of thereof in the patent in to the claimed methods herein for improving the efficacy of a pharmaceutical by percutaneously

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administering the same composition to a male subject since these methods between in the patent and in the instant application are seen to substantially overlap.

Thus, the instant claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are seen to be obvious over the claims 18-42 of U.S. Patent No. 6,503,894.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 of copending Application No. 10/033,101.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application are drawn to methods of transdermally delivering the same composition to a male subject. The claim of the



instant application is drawn to methods for improving the efficacy of a pharmaceutical comprising percutaneously administering a composition to a male subject. One having ordinary skill in the art at the time the invention was made would have been motivated to percutaneously administer the same composition in methods of transdermally delivering the same composition to a male subject in the copending Application to the claimed methods for improving the efficacy of a pharmaceutical pharmaceutical by percutaneously administering the same composition to a male subject since these methods between in the copending application and in the instant application are seen to substantially overlap.

Thus, the instant claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are seen to be obvious over the claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 of copending Application No. 10/033,101.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
January 10, 2003

  
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